

Country Quality Manager & Qualified Person

Job ID
REQ-10089052

九月 30, 2026

T ü rkiye

摘要

- To ensure that the product, processes and procedures conforms with GxP and local specifications and that production activity is compliant with Novartis quality policy and GxP requirements.
- To ensure that relevant documentation is up-to-date and archived correctly. Ensure “state of the art” GxP know-how and future trends in the field of GxP

About the Role

Major Accountabilities:

- Manage the implementation and maintenance of a local Quality Management System that complies with local regulatory requirements and the Novartis Quality Manual and policies.
- Ensure timely implementation of updates to applicable local guidelines and requirements, including GMP, GDP, and barcode and 2D barcode requirements for human medicinal

products.

- Fulfil the duties and responsibilities of the Qualified Person for the Farmanova entity, including performing batch release checks and approving relevant products.
 - Perform release activities for supporting clinical products.
 - Approve artwork changes for Farmanova products.
 - Collaborate with all Country functions responsible for GxP and health-regulated activities to ensure the efficient and effective operation of the Country Quality System.
 - Establish and maintain effective communication with local Health Authorities and the Country organisation, ensuring that all commitments are appropriately tracked and closed on time.
 - Manage product recalls/ mock recalls in accordance with local regulatory requirements and the Novartis Quality Manual, and support or participate in related activities as required.
 - Participate in the evaluation and investigation of quality deviations and complaints, ensuring that appropriate corrective and preventive actions (CAPAs) are established.
 - Lead escalation processes and follow up on required actions.
 - Review and approve standard operating procedures (SOPs).
 - Manage changes that affect or could affect product quality and serve as the Change Management Lead for the Country organization.
 - Perform Marketing Authorisation Holder (MAH) reviews of relevant Annual Product Quality Reviews (APQRs), prepare the annual APQR plan, evaluate trends, and follow up on actions.
 - Ensure the annual Quality Plan is prepared, and its actions are followed through to completion.
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- Lead Quality System and GMP audits conducted by Health Authorities, Novartis Global functions, or outsourced service providers.
 - Lead training and self-inspection activities in accordance with local and global requirements.
 - Ensure compliance with quality risk management requirements, including the identification, anticipation, and assessment of quality risks; development and implementation of appropriate action plans; and preparation of the annual risk assessment plan and report.
 - Report quarterly Key Quality Indicators within the scope of responsibilities, monitor performance, and ensure that gaps are appropriately addressed to mitigate risk. · Prepare annual and quarterly review reports, including the Annual Quality Review Report, Training Plan Report, and Business Review Meeting materials.
 - Provide quality oversight of the third-party warehouse and maintain effective collaboration with relevant partners.
 - Lead vendor management activities, including quarterly review meetings, preparation of the Approved Supplier List, qualification processes, and Quality Assurance Agreement (QAA) preparation.
 - Actively drive operational excellence projects in alignment with global process streams and the Country Quality strategy.
 - Ensure implementation and maintenance of the ISO 9001:2015 Quality Management System within the T ü rkiye Country organization. ·
 - Act as the Quality Operations Partner (QOP) single point of contact within the Country Quality organization. ·
 - Serve as Culture Ambassador Lead for Country Quality T ü rkiye within the region. ·
 - Act as deputy to the Country Quality Head T ü rkiye.

Key Competencies

- Proactive mindset
- Resilience and adaptability
- Business acumen
- Curiosity and continuous learning
- Sound judgement and decision-making
- Strong project management skills

Role Requirements

- University degree in Pharmacy, Chemical Engineering, Chemistry, or a related discipline.
- Advanced written and verbal communication skills in English are required.
- At least 6 years of Quality experience within the pharmaceutical industry.
- At least 2 years of experience at a pharmaceutical manufacturing site in Quality Control, Quality Assurance, or Manufacturing Quality.
- Strong knowledge of the regulations, guidelines, and good practices applicable to Country organisation operations.
- End-to-end process orientation and a continuous-improvement mindset.
- Strong knowledge of current Good Manufacturing Practice (cGMP), relevant GxP requirements, and pharmaceutical distribution processes.
- Ability to manage multiple priorities and consistently meet deadlines.
- Excellent interpersonal, communication, and presentation skills.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

部門
Operations

Business Unit
Quality

地点
T ü rkiye

站点
Istanbul Ata ş ehir

Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sa ğ l ı k, G ı da ve Tar ı m Ü r ü nleri San. Ve Tic. A. Ş .

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6ac72f9332013921341093", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop:
false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options:
}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu:
false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets:
['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(kPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default:
bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default:
alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled:
false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation =
{ position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if
(kPlayer.plugins["hotspots"]) { config.plugins["playkit-js-hotspots"] = { disable: true }; } if
(kPlayer.plugins["moderation"]) { config.plugins["playkit-js-moderation"] = { disable: true }; } if
(kPlayer.plugins["info"]) { config.plugins["playkit-js-info"] = { disable: true }; } if
(kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if
```

```
(kPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {};  
config.plugins.googleTagManager.customEventsTracking = {};  
config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';  
config.plugins.googleTagManager.customEventsTracking.custom = [];  
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:  
false, playlistEvents: false, castEvents: false } }; }
```

```
// Ensure the global player registry array always exists, regardless of embed type.  
window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise =  
thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() returns a  
Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to  
capture the player directly. thumbEmbedPromise .then(function(player) {  
window.kalturaPlayerVideos.push(player); // Notify kalturadatalayer.js that a new player is ready so  
it can // attach custom event listeners immediately, regardless of when // the user clicked the  
thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', {  
detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) {  
console.error(e.message) }
```

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